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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,856	07/25/2001	David H. Mack	003848.00091	4786

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[REDACTED] EXAMINER

MAHATAN, CHANNING

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1631

IS

DATE MAILED: 07/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/911,856	MACK, DAVID H.	
	Examiner	Art Unit	
	Channing S. Mahatan	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 May 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-107 is/are pending in the application.
- 4a) Of the above claim(s) 10-105 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-9, 106 and 107 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on 02 May 2003 is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.

- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

APPLICANTS' ARGUMENTS

Applicants' arguments in Paper No. 13, filed 02 May 2003, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-9, 106, and 107. This application contains claims 10-105 drawn to an invention nonelected without traverse in Paper No. 10. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 C.F.R. § 1.144) See M.P.E.P. § 821.01.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

LACK OF ENABLEMENT

Claims 1-9, 106, and 107 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1 (lines 10-11) and all claims dependent therefrom recites the step of "analyzing said cluster map to generate gene network causal models defining regulatory relationships among said genes" which is not enabled and thus failing to provide guidance to practice. Applicants argue the "specification need not provide procedural steps for analyzing a cluster map because

such methods were well known in the art and were publicly available at the time the application was filed" (Paper No. 13, filed 02 May 2003, page 22) with respect to "analyzing said cluster map to generate gene network causal models defining regulatory relationships among said genes" (instant claim 1, lines 10-11), which is found unpersuasive. This assertion is unsupported by the specification and art of record, which do not disclose the generation of any gene network causal model defining regulatory relationships. The absence of specific procedures and/or steps to analyze a cluster map to generate gene network of causal models fails to provide sufficient guidance for one of skill in the art to practice the claimed invention.

For example, Schena et al. (Parallel human genome analysis: Microarray-based expression monitoring of 1000 genes. Proceedings of the National Academy of Sciences USA, Volume 93, October 1996, pages 10614-10619) reports the use of nucleic acid arrays for gene expression monitoring, biological investigation, and gene discovery. Schena et al. lists differentially expressed genes in Tables 1 and 2 by clone name, array position, fluorescence value, sequence identity, and accession number, wherein said genes are grouped (clustered) by expression levels. Scientific Software International, Inc. (LISREL Historical Background, Copyright 1997-2000, pages 1-3) provides a historical background of the LISREL program indicating the application of LISREL in various areas of experimental studies by formulating, fitting, and testing such relationships wherein rules (set forth by the experimenter) determine the linear relationship between variables. Further, Scientific Software International, Inc. state, "linear structural analysis includes algebraic formulation of the model in addition to the path diagram representation" (page 1, line 33-34). Absent from the instant application guidance (i.e. rules), algebraic algorithm(s), and path diagram representation for one of skill in the art to

analyze the gene expression information provided by Schena et al. and generate a gene network causal model (i.e. using LISREL) thereby defining regulatory relationships among genes.

Additionally, the specification states “LISREL is a very general approach for causal model analysis” (page 40, lines 6-13) and no further rules/steps/procedures are indicated as to how to apply it to the particular problem at hand.

As reiterated in the previous office action (Paper No. 11, mailed 02 January 2003) “no gene network causal models are generated from the experimental work in the specification (pages 42-63)”, thus, requiring undue experimentation to develop an algorithm that analyzes a cluster map to generate a gene network model defining regulatory relationships among said genes. An individual skilled in the art would not have been informed as to what to do or how to adapt programs known in the art unless some type of specific procedure is set forth. Applicants are invited to explain where in the specification the known techniques for analyzing cluster maps to generate gene network causal models defining regulatory relationships among genes are disclosed or provide prior art documenting these applications.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 106, and 107 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as necessitated by amendment.

VAGUE AND INDEFINITE

Claim 1 and all claims dependent recite the phrase “the cluster map categorizes genes according to similarity in unchanged, increased, or decreased expression” which implies some range or degree of similarity for the categorization. It is unclear the range or degree of similarity that is considered to be unchanged, increased, or decreased (i.e. percentage above or below unchanged expression). Additionally, if differences in increased or decreased categorization levels are intended it unclear that these categorization levels exist and the degree of similarity that distinguishes each level from one another. Clarification of the metes and bounds, via clearer claim language, is requested.

No Claims Are Allowed.*ACTION IS FINAL, AS NECESSITATED BY AMENDMENT*

Applicants’ amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date:

July 11, 2003

Examiner Initials:

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
GROUP 1600
A11631